

Application Number 10/731.868  
Amendment dated November 28, 2005  
Responsive to Office Action mailed July 28, 2005

### **REMARKS**

This reply is responsive to the Office Action dated July 28, 2005. Applicant does not make any amendments to the claims by way of this reply. Claims 1-21 remain pending. Of those claims, claims 13, 14 and 18-21 have been withdrawn in response to a restriction requirement.

### **Claim Rejections under 35 U.S.C. § 102**

In the Office Action, the Examiner rejected claims 1, 5-10, 12, 15 and 16 under 35 U.S.C. § 102(e) as being anticipated by U.S. Pat. No. 6,427,086 to Fischell et al. (hereinafter "Fischell"). The Examiner also rejected claims 1-3, 5-7, 9, 10, 12 and 15-17 under 35 U.S.C. § 102(e) as being anticipated by U.S. Pat. No. 6,648,914 to Berrang et al. (hereinafter "Berrang"). The Examiner also rejected claims 1-4, 7 and 15 under 35 U.S.C. § 102(e) as being anticipated by U.S. Pat. Application Pub. No. 2003/0109903 by Berrang et al. (hereinafter "Berrang application"). Applicant respectfully traverses these rejections. The applied references fail to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(e), and provide no teaching that would have suggested the desirability of modification to include such features as required to support a rejection under 35 U.S.C. § 103(a).

For example, the Examiner rejected independent claim 1 under 35 U.S.C. § 102(e) as being anticipated by each of Fischell, Berrang and the Berrang application. However, each of these references fails to disclose at least two elements of independent claim 1. In order to support an anticipation rejection under 35 U.S.C. § 102(e), it is well established that a prior art reference must disclose each and every element of a claim. This well known rule of law is commonly referred to as the "all-elements rule."<sup>1</sup> If a prior art reference fails to disclose any element of a claim, then rejection under 35 U.S.C. § 102(e) is improper.<sup>2</sup>

First, none of the applied references disclose creating a pocket between the scalp and the skull. Second, none of the applied references teach placing at least a portion of a low-profile

<sup>1</sup> See *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 USPQ 81 (CAFC 1986) ("it is axiomatic that for prior art to anticipate under § 102 it has to meet every element of the claimed invention").

<sup>2</sup> *Id.* See also *Lewmar Marine, Inc. v. Bariant, Inc.* 827 F.2d 744, 3 USPQ2d 1766 (CAFC 1987); *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (CAFC 1990); *C.R. Bard, Inc. v. MP Systems, Inc.*, 157 F.3d 1340, 48 USPQ2d 1225 (CAFC 1998); *Oney v. Ratliff*, 182 F.3d 893, 51 USPQ2d 1697 (CAFC 1999); *Apple Computer, Inc. v. Articulate Systems, Inc.*, 234 F.3d 14, 57 USPQ2d 1057 (CAFC 2000).

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implantable medical device in the pocket. Each of these deficiencies in the prior art is discussed with respect to the applied references in more detail below.

Fischell discloses placing an implantable neurostimulator control module into a space in the cranium where cranial bone has been removed.<sup>3</sup> In contrast to the Applicants' claim 1, which requires creating a pocket between the scalp and a skull, Fischell describes cutting the scalp and exposing the cranium.<sup>4</sup> The actual implantation process of a neurostimulation system is described in limited detail in Fischell. Specifically described steps of implantation include shaving the implantation site, making an incision and removing bone to make room for a neurostimulation device.<sup>5</sup> Fischell also describes templates that can be used to mark the cranium prior to removing bone to form a hole that makes room for the neurostimulation device.<sup>6</sup> In this manner, Fischell is consistent with prior art implantation techniques that do not require creating a pocket between the scalp and a skull, but instead require exposing the area of the cranium on which an implantable medical device is to be placed. Furthermore, because it would be practically difficult to remove bone in a pocket formed between a scalp and skull and also difficult to use a template within a pocket, one of ordinary skill in the art would not seek to modifying the disclosure of Fischell to include creating a pocket and placing at least a portion of an implantable medical device in the pocket.

Berrang is similar to Fischell in that it also fails to teach creating a pocket between the scalp and skull of a patient. Berrang describes making an incision to create a flap behind the ear of a patient to expose a location on the patient's skull, and placing the implant on the exposed skull.<sup>7</sup> This is in contrast to the limitations of claim 1, which require creating a pocket between the scalp and the skull and placing at least a portion of a low-profile implantable medical device in the pocket.

Berrang application likewise fails to teach creating a pocket between the scalp and skull of a patient. As with the other cited references, Berrang application provides limited details on techniques for implanting a medical device. The description given in Berrang application is

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<sup>3</sup> Fischell, abstract.

<sup>4</sup> Fischell, abstract.

<sup>5</sup> Fischell, col. 31, lines 34-37.

<sup>6</sup> Fischell, col. 36, lines 22-33.

<sup>7</sup> Berrang, Fig. 3, col. 13, lines 40-64.

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consistent with the other cited references. Specifically, it requires making a surgical incision to create a skin flap and pulling back the skin flap to expose an area of a patient's skull on which an implantable medical device is to be implanted.<sup>8</sup> This is in contrast to the limitations of claim 1, which require creating a pocket between the scalp and the skull and placing at least a portion of a low-profile implantable medical device in the pocket.

For at least these reasons, none of the applied references teach each limitation of claim 1. Furthermore, the subject matter of claim 1 would not have been obvious to one of ordinary skill in the art at the time of the Applicants' invention. Therefore, claim 1 and dependent claims 2-17 are allowable over the cited prior art.

The cited references also fail to disclose each of the limitations of dependent claim 2. Claim 2 recites the method of claim 1, wherein the low-profile implantable medical device comprises: a first module that includes control electronics within a first housing, a second module that includes a second housing and a flexible overmold that at least partially covers the first and second housings.

The Examiner cited Berrang and Berrang application in the rejection of claim 2. However, each of the Berrang references fail to disclose first and second housings, as required by claim 2. Instead Berrang discloses a segmented device with a single housing 27 (FIG. 2). Berrang application also clearly illustrates a device comprising a single housing comprising plates 2 and 3.

For at least these reasons, in addition to failing to disclose the limitations of independent claim 1, none of the applied references teach each limitation of claim 2. Furthermore, the subject matter of claim 2 would not have been obvious to one of ordinary skill in the art at the time of the Applicants' invention. Therefore, claim 2 is allowable in its current form over the cited prior art.

As another example, the cited references fail to disclose or suggest an angle between the periphery of the implantable medical device and the skull is approximately 135 degrees, as required by claim 6. The Examiner has cited no disclosure related to this requirement of claim 6 in any of the references. Instead, the Examiner appears to merely conclude that it is disclosed.

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<sup>8</sup> Berrang application, paragraph [0056].

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This is improper. Applicant respectfully requests that the Examiner enter evidence into the record of what specifically the Examiner believes is a teaching or suggestion of this requirement within in the prior art, so that Applicant may rebut such evidence.

The applied references fail to disclose each and every limitation of claims 1, 2 and 6. For at least this reason the Examiner has failed to establish a prima facie case of anticipation of claims 1-10, 12 and 15-17 under 35 U.S.C. § 102(e). Withdrawal of these rejections is requested.

#### **Claim Rejections under 35 U.S.C. § 102**

In the Office Action, the Examiner rejected claim 11 under 35 U.S.C. § 103(a) as being unpatentable over any of Fischell, Berrang or Berrang application in view of Official Notice. Applicant respectfully traverses this rejection. As discussed above, each of Fischell, Berrang and Berrang application fail to disclose or suggest a number of requirements of independent claim 1. For at least this reason, the Examiner has failed to establish a prima facie case of non-patentability of claim 11 under section 103. Withdrawal of this rejection is requested.

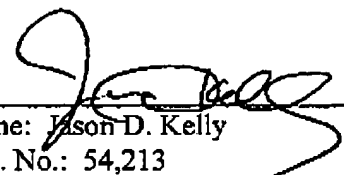
#### **CONCLUSION**

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

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11/28/05  
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